

***Prosecution History Summary***

- Claims 1-59 are pending.

***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 05/21/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Some of the foreign documents were not considered because no translations were provided.

**DETAILED ACTION**

***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “input buttons” has been used to designate both 2070C (figure 14). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (U.S. Patent No. 5,019,974).

5. As per claim 1, Beckers teaches a blood glucose monitoring system, comprising:

a. a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level (**Beckers: col. 6, 63-col. 8, 14**);

b. a programmable microprocessor-based portable unit (**Beckers: col. 2, 27-37**);

c. a digital data storage medium, the medium

A. readable by said programmable micro-processor based unit (**Beckers: col. 2, 27-37**);

and

B. tangibly embodying therein a program of instructions executable by said programmable microprocessor-based portable unit, said program of instructions including instructions for signal processing in response to signals generated based upon said digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage (**Beckers: col. 2, 27-37; col. 3, 38-50**);

d. a signal interface connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded blood glucose signals supplied by said blood glucose monitor to said programmable microprocessor-

based portable unit (**Beckers: col. 11, 12-19**); and  
e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions (**Beckers: col. 11, 12-19**).

It would have been obvious to modify the teachings of Beckers with the motivation of providing a system for patients with diabetes to track the changes made in health due to changing age or daily routine (**Beckers: col. 1, 19-29**).

6. As per claim 2, Beckers teaches wherein said microprocessor-based portable unit is a palm-top computer (**Beckers: figure 1**).

The motivation to modify is the same as claim 1.

7. As per claim 3, Beckers teaches the blood glucose monitor for receiving a test strip including a reagent impregnated portion having blood applied thereto (**Beckers: col. 6, 19-36**).

The motivation to modify is the same as claim 1.

8. As per claim 8, Beckers teaches at least a component of said signal interface being connectable with a second device, other than said blood glucose monitor, in signal communication with said programmable microprocessor-based portable unit for coupling further signals supplied by said second device to said programmable microprocessor-based portable unit (**Beckers: claim 12(a)**).

The motivation to modify is the same as claim 1.

9. As per claim 9, Beckers teaches wherein said programmable microprocessor-based portable unit comprises an interactive interface, including:

1) a display for displaying information (**Beckers: col. 11, 20-22**);

2) a plurality of switches operable for interactively controlling said microprocessor-based interactive portable unit and for manipulating said information displayed on said display (**Beckers: figure 1**); and

3) circuit means coupled to said plurality of switches for generating signals in response to said operation of said switches (**Beckers: col. 2, 38 to col. 3, 20**).

The motivation to modify is the same as claim 1.

10. As per claim 17, Beckers teaches A method of performing diabetes self-care with a system of integrated electronic devices, comprising:

- powering a portable blood glucose monitor with one or more batteries (**Beckers: col. 6, 19-22; col. 8, 16-22**);
- receiving an amount of blood sufficient for a blood glucose monitor to run a blood glucose test sequence (**Beckers: col. 6, 23-27**);
- controlling the blood glucose test sequence (**Beckers: col. 6, 19-36**);
- computing a blood glucose level (**Beckers: col. 6, 34-36**);
- signal coupling the blood glucose monitor to a portable microprocessor-based electronic device via a first data port (**Beckers: col. 2, 12-20**);
- transmitting blood glucose test results from said blood glucose monitor to said portable microprocessor-based device (**Beckers: col. 2, 34-37**);
- running program instructions stored in a memory of the portable microprocessor-based device for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage (**Beckers: col. 2, 27-53**); and
- recording blood glucose test results and insulin dosage information in a memory of the portable

microprocessor-based device, said memory also containing programming for establishing a data protocol that allows digital data signal processing, and for performing said analysis of blood glucose (**Beckers: col. 2, 27-53**).

The motivation to modify is the same as claim 1.

11. As per claim 18, Beckers teaches the receiving including inserting a test strip into a receptacle of the blood glucose monitor; and applying a drop of blood to the strip (**Beckers: col. 6, 23-27**).

The motivation to modify is the same as claim 1.

12. As per claim 19, Beckers teaches further comprising displaying the blood glucose level on a display (**Beckers: col. 6, 34-36**).

The motivation to modify is the same as claim 1.

13. As per claim 27, Beckers teaches wherein said portable microprocessor-based device comprises an interactive interface including a display screen and a plurality of switches including a pair of spaced-apart push button switches and another pair of switches, and the method further comprises interactively controlling said portable microprocessor-based device by manipulating said switches (**Beckers: figure 1**).

The motivation to modify is the same as claim 1.

14. As per claim 28, Beckers teaches a blood glucose monitoring system, comprising:  
a. a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of said blood glucose level (**Beckers: col. 6, 63-col. 8, 14**);  
b. a programmable microprocessor-based portable unit (**Beckers: col. 2, 27-37**);

- c. digital data storage media tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon said digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage and further for performing a test sequence to confirm that the system is operating properly (**Beckers: col. 3, 23-50**);
- d. a signal interface connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded health signals supplied by said blood glucose monitor to said programmable microprocessor-based portable unit (**Beckers: col. 11, 12-19**); and
- e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions (**Beckers: col. 11, 12-19**).

The motivation to modify is the same as claim 1.

15. As per claim 40, Beckers teaches A system of interconnected devices for performing diabetes self-care, comprising:
- (a) a blood glucose monitor, including:
    - (i) a receptacle for receiving an amount of blood sufficient for the monitor to run a blood glucose test sequence (**Beckers: col. 6, 24-27**);
    - (ii) processing circuitry for controlling a blood glucose test sequence and computing a blood glucose level (**Beckers: col. 6, 28-36**),
    - (iii) a battery compartment for holding a battery for powering the blood glucose monitor (**Beckers: col. 8, 16-22**), and

(iv) a first data port for signal coupling to another electronic device (**Beckers: col. 10, 30-32**);  
and

(b) a portable microprocessor-based device signal coupled with the blood glucose monitor,  
including:

(i) a second data port for signal coupling with the first data port and receiving blood glucose test results from said blood glucose monitor (**Beckers: col. 9, 25-30**),

(ii) a microprocessor that runs according to program instructions stored in a memory for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage (**Beckers: col. 3, 38-50**),

(iii) a memory for recording the recorded blood glucose test results and insulin dosage information therein, and for containing programming for establishing a data protocol that allows digital data signal processing, and for performing analysis of blood glucose (**Beckers: col. 3, 38-50**).

The motivation to modify is the same as claim 1.

16. Claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48, 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckers (U.S. Patent No. 5,019,974) in view of Reference U.

17. As per claim 4, Beckers does not explicitly teach the program of instructions including instructions for monitoring whether a sufficient amount of blood has been applied to said reagent impregnated portion of the test strip.

Reference U teaches the program of instructions including instructions for monitoring whether a sufficient amount of blood has been applied to said reagent impregnated portion of the test strip (**U: p. 253, col. 2, para. 5**).

It would have been obvious to one of ordinary skill in the art to combine the teachings with the motivation of giving the patients a greater responsibility for managing their diabetes (U: **p. 253, col. 1, para. 1**).

18. As per claim 5, Beckers does not explicitly teach the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor.

Reference U teaches the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor (U: **p. 265, col. 2, para. 3**).

The motivation to combine the teachings is the same as claim 4.

19. As per claim 6, Beckers does not explicitly teach the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor.

Reference U teaches the program of instructions further including instructions for monitoring whether said test strip is properly inserted into the monitor (U: **p. 257, col. 1, para. 2**).

The motivation to combine the teachings is the same as claim 4.

20. As per claim 7, Beckers does not explicitly teach the program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly.

Reference U teaches the program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly (U: **p. 257, col. 1, para. 2**).

The motivation to combine the teachings is the same as claim 4.



21. Claims 10-16 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.
22. Claims 20-26 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.
23. Claims 29-31 recite substantially similar limitations as those already addressed in claims 3-5, and, as such, are rejected for similar reasons as given above.
24. Claim 32 recite substantially similar limitations as those already addressed in claim 2, and, as such, are rejected for similar reasons as given above.
25. Claims 33-34 recite substantially similar limitations as those already addressed in claims 8-9, and, as such, are rejected for similar reasons as given above.
26. Claims 35-38 recite substantially similar limitations as those already addressed in claims 2-5, and, as such, are rejected for similar reasons as given above.
27. Claim 39 recite substantially similar limitations as those already addressed in claim 8, and, as such, are rejected for similar reasons as given above.
28. Claims 41-42 recite substantially similar limitations as those already addressed in claims 18-19, and, as such, are rejected for similar reasons as given above.
29. Claims 43-50 recite substantially similar limitations as those already addressed in claims 2-9, and, as such, are rejected for similar reasons as given above.
30. Claims 51-52 recite substantially similar limitations as those already addressed in claims 18-19, and, as such, are rejected for similar reasons as given above.
31. Claims 53-59 recite substantially similar limitations as those already addressed in claims 2-8, and, as such, are rejected for similar reasons as given above.

***Conclusion***

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Garcia et al. (U.S. Patent No. 4,627,445) discloses a glucose medical monitoring system.

-Allen, III (U.S. Patent No. 4,731,726) discloses a patient-operated glucose monitor and diabetes management system.

-DeMarzo (U.S. Patent No. 4,953,552) discloses a blood glucose monitoring system.

-Kahn et al. (U.S. Patent No. 5,251,126) discloses a diabetes data analysis and interpretation method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571)270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRR

/C Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626